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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

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CAROLINE NASH
NASH & TITUS, LLC
21402 UNISON ROAD
MIDDLEBURG, VA 20177

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,108	SHERMAN, KENNETH ELIOT	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-17 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-17 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is responsive to the communication received May 10, 2005. Claims 1, 3-8, 10-17 and 19-24 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 10-17 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is defined by a number of factors. These factors include: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Applicants claim a composition, and a method of using said composition, for treatment of hepatitis C virus ("HCV") infection comprising an immune-system potentiating amount of thymosin, or an immune-system potentiating amount of fragments of thymosin, in combination with an anti-hepatitis C viral effective amount of at least one interferon. Thus, the nature of the invention is a combination therapy for HCV infection comprising interferon ("IFN") and thymosin. At the time the parent Application was filed, the state of the art was such that thymosin/IFN combination therapy was being explored as a means for enhancing cytotoxic T-cell activity in the treatment of tumors and hepatitis B virus ("HBV") infection. (see e.g. Favalli, C., Cancer Immun. (1985) Vol. 20). Research at the time indicated that efficacy depended on the sequential administration of thymosin followed by a single injection of interferon days after the administration thymosin

(Id.). Based on the very different modes of pathogenesis of HBV, cancer and HCV, one skilled in the art cannot begin to predict how a non-specific treatment cancer or HBV will impact HCV infection. Applicants acknowledge this in their remarks where it is stated that at one skilled in the art could not have anticipated that a treatment for a DNA virus (i.e. HBV) would have efficacy in the treatment of HCV (i.e. an RNA virus). Applicants note that the virus' different modes of infection, and interaction with host cell processes, does not allow the skilled artisan to to predict how a treatment for one virus will affect infection by the other. The content of the specification, however, provides little direction on how this lack of predictability can be overcome. Although the specification offers Example 5 as a working example, it appears that the results and procedures disclosed there are merely prophetic – it does not appear the experiment was actually conducted nor favorable results obtained. Based on the scant content of the disclosure and the unpredictability of using thymosin in combination with IFN, one skilled in the art would have to perform undue experimentation in order to practice the claimed invention.

Response to Arguments

Enablement

Applicants argue the specification teaches one of ordinary skill in the art how to treat HCV infection using a combination therapy comprising interferon and thymosin, or a thymosin fragment. Applicants point to the specific administration routes and administration schedules disclosed in the specification. These teachings however do not enable the claimed method.

The previous Office Action held the claimed method was not enabled because the outcome of an HCV therapy based on thymosin in combination with interferon was unpredictable. The Office Action noted that the state of the art at the time the application was filed only taught that thymosin and interferon could to be used treat neoplasms and HBV infection. These teachings however did not allow one skilled in the art to predict how the claimed treatment would work on HCV.

Applicants note that whether the treatment works in HBV has no relevance to the whether the specification enables the claimed method of treating HCV. The Examiner agrees. However, this difference

only makes the outcome of the claimed treatment more unpredictable. That is, the skilled artisan could not use the teachings that relate to HBV to use the claimed invention to treat HCV infection. Therefore, there is nothing other than the specification to teach the skilled artisan how to use alpha interferon and thymosin to treat HCV. However, as noted in the Office Action, the specification provides little direction. There are no working examples of the invention, or any other data, that teach the combination of thymosin and alpha interferon are effective in treating HCV. The enablement rejection of the claims therefore maintained.

Note that a declaration in compliance with 37 C.F.R. 1.132 can be used to overcome this rejection. Such a declaration should include data that shows the claimed treatment reduces serum levels of HCV antigen, HCV antibody or HCV oligonucleotides.

Written Description

The written description rejection of claims 1, 3-8, 10-17 and 19-24 is withdrawn in view of Applicants' remarks.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

James C. Housel 9/6/05

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

TMB 8/31/05